REMARKS

Claims 1-69 are pending. Claims 2, 7-46, 48, 49, and 52-69 are withdrawn. Claims 1, 47, and 50 are amended. The amendments to the claims find support in the specification at pages 22 and are discussed in further detail below.

Objections

The Office Action states that claim 1 is objected to because the comma after "SEQ ID NO: 2" should be replaced with a period. Applicants have amended the claims accordingly, and request that the rejection be reconsidered and withdrawn.

Rejection of Claims 50 and 51 Under 35 U.S.C. §112, Second Paragraph

The Office Action states that claims 50 and 51 are rejected under §112, second paragraph for the recitation of "complementary" and "corresponding." Applicants traverse the rejection in view of the amended claims.

The Office Action states that the term "complementary" renders the claims indefinite because the definition of "complementary" is based on a definition of "specific hybridization," which, itself, is allegedly vague and indefinite. Applicants maintain that one of skill in the art is well versed in complementary sequences and would have a clear understanding of the metes and bounds of the claimed invention. Nevertheless, in order to expedite prosecution, Applicants have amended the claims to require that the recited antisense nucleic acid be "fully complementary." Support for this amendment can be found in the specification at page 22. The scope of the definition of "complementary" includes sequences that are 100% (i.e., fully) complementary. Moreover, the specification states that an example of sequences which fall under the definition of "complementary" include the sequences 5'-TATAC and 5'-GTATA. The recited sequences are fully complementary to each other. Thus, the specification provides support for the claimed antisense molecule to be fully complementary to the mRNA transcript of SEQ ID NO: 1.

The Office Action also states that the claims are rejected for the recitation of the term "corresponding." The Office Action states that since "corresponding" is defined in the specification in terms of sequences being "complementary", asserted by the Office Action to be indefinite itself, the term "corresponding" is likewise indefinite. Applicants traverse the rejection in view of the amended claims.

While Applicants believe that one of skill in the art would fully understand the metes and bounds of the term "corresponding," solely for the purpose of expediting prosecution in this case, Applicants have amended the claims to replace the term "corresponding" with the phrase "mRNA sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No. 1". Support for this amendment can be found in the specification as filed on page 22.

Based on the foregoing, the claims are clear and definite. Applicants accordingly request that the rejections under §112, second paragraph be reconsidered and withdrawn.

Rejection of Claims 1, 3-6, 47, 50, and 51 Under 35 U.S.C. §112, First Paragraph

Written Description

The Office Action states that claims 1, 3-6, 47, 50, and 51 are rejected under §112, first paragraph for failing to comply with the written description requirement. Applicants disagree and traverse the rejection.

The Office Action states that claims 50 and 51 do not satisfy the written description requirement with respect to the recitation of sequences "complementary" to an mRNA sequence "corresponding" to SEQ ID NO: 1. As noted above, the claims have been amended to require that the claimed antisense molecule is "fully complementary" and have further amended claim 50 to delete reference to "corresponding" and to, instead, clarify that the recited mRNA sequence is transcribed from the sequence of SEQ ID NO: 1. As such, the claims do not encompass, as

asserted by the Office Action, a polynucleotide sequence that has any level of sequence complementarity to SEQ ID NO: 1. One of skill in the art would not doubt that Applicants were in possession of a sequence fully complementary to the mRNA sequence that results from the transcription of SEQ ID NO: 1, since the full and complete structure of such a sequence can be envisioned based on an understanding of basic nucleic acid base pairing rules.

With respect to claim 1 and its dependents, Applicants contend that the claims, as amended are in full satisfaction of the written description requirement. The Office Action acknowledges that the specification contains a sufficient description of a polynucleotide sequence comprising SEQ ID NO: 1. The Office Action states, however, that because SEQ ID NO: 2 is a fragment of SEQ ID NO: 1 and the claims do not recite a function for a polynucleotide comprising SEQ ID NO: 2, that the recitation of a polynucleotide "comprising SEQ ID NO: 2" encompasses a large number of variants and mutants not described in the specification. The Office Action acknowledges that the specification teaches that SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase, but notes that this function is not recited in the claims with respect to sequences comprising SEQ ID NO: 2. Accordingly, to expedite prosecution, Applicants have amended claim 1 to recite that the recited polynucleotide comprising SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase. Thus, the claims relate, not to all possible variants of SEQ ID NO: 1 as asserted by the Office Action, but to a sequence comprising SEQ ID NO: 2 having the function of binding to and inhibiting telomerase. One of skill in the art would clearly understand Applicants to have been in possession of the recited polynucleotide sequences and Applicants, accordingly, request that the rejection be reconsidered and withdrawn.

Enablement

The Office Action states that claims 1, 3-6, 47, 50, and 51 are rejected under §112, first paragraph for lack of enablement. The Office Action states that the claims are enabled for a polynucleotide sequence comprising the sequence of SEQ ID NO: 1,

but contends that the specification is not enabling for a polynucleotide sequence comprising SEQ ID NO: 2.

Breadth of the Claims

As noted above, the claims have been amended to recite "comprising the sequence of SEQ ID NO: 1 or SEQ ID NO: 2 wherein said isolated PinX1 polynucleotide comprising the sequence of SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase" (claim 1), or "fully complementary to the mRNA sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No. 1" (claim 50). The Office Action states that the claims do not define the 5' nucleotides that flank the sequence of SEQ ID NO: 2 or the overall functional activity of the claimed polynucleotide. The fact that the claims are silent as to the polynucleotide sequence 5' of the sequence of SEQ ID NO: 2 does not render the claims non-enabled. As the Office Action acknowledges, SEQ ID NO: 2 is a fragment of SEQ ID NO: 1 that encodes a polypeptide that binds to and inhibits telomerase. To further clarify this point, claim 1 has been amended to include the functional limitation that SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase.

With respect to claims 50 and 51, as described above, the term "complementary" has been modified to "fully complementary" and "corresponding" has been amended to recite an mRNA sequence transcribed from a polynucleotide comprising SEQ ID NO: 1.

Nature of the Invention

The Office Action states that the claims fall into a class of invention that has been characterized as "the unpredictable arts such as chemistry and biology." Clearly, the biological arts cannot be universally unpredictable, otherwise no patents would issue on biological inventions, because no invention would meet requirements of §112. The instant invention is not unpredictable, and relates to polynucleotide molecules comprising specified sequences, recited in the claims by sequence identifier number.

State of the Art

The Office Action correctly states that the specification teaches the sequence of SEQ ID NO: 1, encoding PinX1 and the sequence of SEQ ID NO: 2 coding for a fragment of PinX1 that comprises the telomerase binding domain. With respect to the Office Action's description of the state of the art for SEQ ID NO: 5, Applicants note that claims drawn to SEQ ID NO: 5 are not part of the elected invention, so it is unclear why SEQ ID NO: 5 has been incorporated into the rejection.

Predictability of unpredictability of the art and degree of experimentation

The Office Action states that the prior art acknowledges the unpredictability in modifying the nucleotide sequence of a gene, and that modification of even a single nucleotide within a coding or non-coding sequence can significantly alter the functional properties of that gene. The Office Action states that while the specification teaches that the C-terminal domain of PinX1 is important for telomerase binding activity, the specification does not teach "any particular amino acids therein which are critical for maintaining binding activity and does not teach any particular nucleotides within the full length PinX1 polynucleotide which encode for amino acids that are critical for other functional activities." The Office Action concludes that it is unpredictable "as to how modifying sequences within SEQ ID NO: 1 will effect the overall functional properties of the resulting gene...[or] how adding nucleotides of any identity or length to the terminus of SEQ ID NO: 2...will effect the functional properties of the resulting nucleic acid and encoded polypeptide.

The instant claims have been amended to recite "comprising the sequence of SEQ ID NO: 1 or SEQ ID NO: 2, wherein said isolated PinX1 polynucleotide comprising the sequence of SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase" (claim 1), or "fully complementary to the mRNA sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No. 1" (claim 50), and thus, no longer recite polynucleotides comprising the sequence of SEQ ID NO: 1 or 2 or a sequence corresponding to SEQ ID NO: 1. As amended, the claims relate to a polynucleotide comprising all of either SEQ ID NO: 1 or SEQ ID NO: 2, thus, the issue

of predictability as to what sequences within SEQ ID NO: 1 or 2 can be modified is moot with respect to the enablement analysis. With respect to the assertion by the Office Action that the specification does not teach particular amino acids encoded by SEQ ID NO: 2 that are critical for maintaining telomerase binding activity, again, this point is moot as the claims recite a polynucleotide comprising the sequence of SEQ ID NO: 2, and not sub-sequences thereof. In addition, the claims have been amended to require that a sequence comprising SEQ ID NO: 2 must maintain telomerase binding and inhibitory function.

With respect to the assertion that the specification does not provide guidance as to how adding nucleotides of any identity or length to the terminus of SEQ ID NO: 2 will effect the functional properties of the encoded polypeptide, Applicants submit that the claims are enabled as currently written. Claim 1 and its dependents recite a polynucleotide comprising the sequence of SEQ ID NO: 2 encoding a polypeptide that binds to and inhibits telomerase. The specification teaches that SEQ ID NO: 2 encodes the 74 C-terminal amino acid residues of PinX1 that are required for binding to Pin2/TRF1 (page 66). The specification teaches at page 42-51 how one of skill in the art would determine telomerase function and activity. Thus, if one of skill in the art desired to add additional nucleotides to the sequence of SEQ ID NO: 2 (taught as encoding the critical amino acid residues for telomerase binding and inhibition), they could do so and then follow the teachings of the specification to determine whether the additional residues altered the function of the polypeptide encoded by SEQ ID NO: 2. Such testing is merely routine and does not amount to undue experimentation, particularly in view of the guidance in the specification. That is, by teaching the sequence of SEQ ID NO: 1, the specification teaches an example of additional sequence that can be added to SEQ ID NO: 2, while maintaining telomerase binding activity. One of skill in the art could use the sequence of SEQ ID NO: 1 as a model for additional sequence to add to SEQ ID NO: 2, if such addition were desired, while maintaining the recited function. Thus, the specification teaches one of skill in the art how to make and use a polynucleotide comprising the sequence of SEQ ID NO:2 encoding a polypeptide that binds to and inhibits telomerase. With respect to the SEQ

ID NO: 1, the Office Action admits that the specification is enabling for a polynucleotide sequence comprising SEQ ID NO: 1 as presently claimed.

Amount of Direction/Guidance and Presence of Working Examples

The Office Action states that the specification does not provide guidance as to how to predictably make and use nucleic acids comprising any portion of SEQ ID NO: 1 or 2, flanked by nucleotides of any length and identity. The Office Action also states that the specification only teaches the sequence of SEQ ID NO:1 and a fragment thereof, SEQ ID NO: 2. The Office Action concludes that the specification does not provide working examples of how to predictably make and use nucleic acids comprising SEQ ID NO: 2. Applicants respectfully traverse the rejection.

As noted above, the claims have been amended to recite a polynucleotide "comprising the sequence of SEQ ID NO: 1 or SEQ ID NO: 2 wherein said isolated PinX1 polynucleotide comprising the sequence of SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase" (claim 1), or "fully complementary to the mRNA sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No. 1" (claim 50). As such, the claims do not encompass "any portion" of SEQ ID NO: 1 or 2. The methods for making nucleic acids are routine in the art, thus, the specification need not expressly teach how to make a nucleic acid comprising SEQ ID NO: 2 because one of skill in the art, given the sequence of SEQ ID NO: 2, would know how to add additional nucleotides, if desired, to the 5' end. In addition, the specification, in teaching the sequence of SEQ ID NO: 1, provides a working example of a polynucleotide sequence comprising the sequence of SEQ ID NO: 2 that retains the recited function. The polynucleotides encompassed by the claims can be readily envisioned, prepared, and characterized by one of ordinary skill in the art according to the methods taught in the specification without having to resort to undue experimentation.

When considered together, the amended claims and teachings of the specification provide ample guidance to permit one of skill in the art to practice the claimed invention without undue experimentation. That is, one of skill in the art could readily make and use a polynucleotide sequence comprising the sequence of SEQ ID

NO: 1 or SEQ ID NO: 2 wherein the isolated PinX1 polynucleotide comprising the sequence of SEQ ID NO: 2 encodes a polypeptide that binds to and inhibits telomerase without undue experimentation. Accordingly, Applicants request that the rejection for lack of enablement be reconsidered and withdrawn.

Rejection of Claims 50 and 51 Under 35 U.S.C. §102(a)

The Office Action states that claims 50 and 51 are anticipated by Liao et al. The Office action states that Liao et al. teaches a nucleic acid molecule with 59% identity to nucleotides 19-1302 of SEQ ID NO: 1. The Office Action concludes that Liao et al., therefore, anticipates the claimed invention. Applicants disagree and traverse the rejection.

At the outset, Applicants note that there is some confusion in the rejection in that the heading states that claims 50 and 51 are rejected, but the rejection goes on to mention claims 3 and 4. Since, claims 3 and 4 depend from claim 1, which is limited to sequences comprising all of SEQ ID NO: 1 or all of SEQ ID NO: 2, and further since these two sequences are not taught by Liao et al., Applicants assume that claims 3 and 4 were mentioned in error. Applicants, accordingly, provide the following remarks with respect to claims 50 and 51.

Claim 50 has been amended to recite an antisense polynucleotide fully complementary to the mRNA sequence transcribed from a polynucleotide comprising SEQ ID NO: 1. Liao et al. does not teach such an antisense molecule. Moreover, Liao et al. does not even teach a polynucleotide comprising SEQ ID NO: 1. Accordingly, Liao et al. do not teach each element of the claimed invention and, therefore, cannot anticipate the claimed invention. Applicants, therefore, request that the rejection be reconsidered and withdrawn.

The Office Action also states that the claims are rejected as anticipated by Hillman et al. Similar to the rejection over Liao et al., it is unclear as to which claims the rejection is being applied, because the Office Action does not clearly state which claims are rejected. Hillman et al. clearly does not teach the sequence of SEQ ID NO: 1 or 2

and, thus, cannot teach a sequence comprising SEQ ID NO: 1 or 2. Thus, Hillman et al. cannot anticipate claim 1 or its dependents. Likewise, Hillman et al. does not teach an antisense polynucleotide fully complementary to the mRNA sequence transcribed from a polynucleotide comprising SEQ ID NO: 1 as recited in claims 50 and 51. Accordingly, Hillman et al. does not teach each element of the claimed invention and, therefore, cannot be said to anticipate the amended claims. Applicants, therefore, request that the rejection be reconsidered and withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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